

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

GEORGE LEHMANN and INSURED
BENEFIT PLANS, INC., Individually and on
Behalf of All Others Similarly Situated,

Lead Plaintiffs,

v.

OHR PHARMACEUTICAL INC., JASON
SLAKTER, SAM BACKENROTH, and IRACH
TARAPOREWALA,

Defendants.

No. 1:18-cv-01284-LAP

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO STRIKE
THE EXTRINSIC EVIDENCE AND RELATED ARGUMENTS THAT DEFENDANTS
SUBMITTED WITH THEIR MOTION TO DISMISS**

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Lead Plaintiffs George Lehmann and Insured Benefit Plans, Inc. (“Plaintiffs”)¹ respectfully submit this memorandum of law in support of their Motion To Strike The Extrinsic Evidence And Related Arguments That Defendants Submitted With Their Motion To Dismiss.²

INTRODUCTION

By moving to dismiss Plaintiffs’ complaint, Defendants availed themselves of the benefits of the automatic discovery stay created by the Private Securities Litigation Reform Act of 1995 (“PSLRA”), 15 U.S.C. § 78u-4(b)(3)(B). Despite invoking the stay’s protections, Defendants nonetheless seek to introduce with their motion certain documents and supposed facts untested by the rigors of discovery and the applicable evidentiary and procedural rules.

Defendants cannot have their cake and eat it too. On a Rule 12(b)(6) motion, all well pleaded facts must be deemed true, and all reasonable inferences must be drawn in favor of the nonmoving party. *See Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 161 (2d Cir. 2000). Further, under Rule 12(d), the Court is precluded from considering evidence outside the pleading unless at least one of two narrow exceptions applies: (1) the **document** is expressly or implicitly incorporated by reference into Plaintiffs’ complaint; or (2) the **adjudicative fact** is properly the subject of judicial notice pursuant to Fed. R. Evid. 201 (“Rule 201”). In either event, the proffered evidence must be admissible **for the purpose it is being offered**.

Tellingly, Defendants did not file a judicial notice motion specifying which adjudicative

¹ Unless stated otherwise, Plaintiffs use the following conventions herein: (1) capitalized terms mean the same as they do in the Plaintiffs’ Amended Class Action Complaint (“AC”), ECF No. 44, and its Table of Defined Terms and Abbreviations, AC at iii-v; (2) all “¶__” references are to the AC; (3) all “Exhibit” or “Ex.” references are to the exhibits attached to the Affirmation Of Aurora Cassirer In Support Of Defendants’ Motion To Dismiss, ECF No. 49; (4) all “Br. at __” references are to the Memorandum Of Law In Support Of Defendants’ Motion To Dismiss The Amended Class Action Complaint, ECF No. 48; (5) all emphases are added to quotations; (6) all internal citations and quotations are omitted; and (7) all “Rule __” references are to the Federal Rules of Civil Procedure.

² Defendants’ motion to dismiss (“MTD”) is available at ECF Nos. 47-49.

facts they seek the Court to decide under Rule 201; nor did Defendants detail how each and every item of extrinsic evidence they proffer is properly before the Court for the purpose they offer the evidence. On this basis alone, Plaintiffs respectfully request that the Court strike all extrinsic evidence that Defendants seek to introduce and all arguments in Defendants' MTD that rely on the evidence. Alternatively, Plaintiffs respectfully request that the Court strike Defendants' extrinsic evidence and related arguments because the evidence is not otherwise properly before the Court on Defendants' MTD.

Specifically, Plaintiffs object to the Court's consideration of the following extrinsic evidence for the purposes that the evidence appears to be submitted: (1) SEC Forms 4 and a Nasdaq Trading Activity Report (Exs. 41-44); (2) SEC filings concerning Ohr's and certain defendants' backgrounds (Exs. 1-3); (3) SEC filings apparently offered for their cautionary language (Exs. 35-40); (4) SEC filings and press releases discussing Squalamine (Exs. 5-10, 14-16, 31-33, 45-46); (5) a December 22, 2016 Seeking Alpha transcript for Ohr's Q4 2016 Earnings Call (Ex. 34); (6) medical articles concerning Squalamine and other drugs (Exs. 4, 17-18, 20, 22-30); (7) certain FDA documents (Exs. 11-13, 21); (8) a July 1, 2014 Seeking Alpha article and certain law firm press releases (Exs. 47-49); and (9) unsworn attorney testimony scattered throughout Defendants' brief.

That said, if the Court admits Defendants' extrinsic evidence and related arguments over Plaintiffs' objections, the Court ***must*** (1) convert Defendants' Rule 12(b)(6) motion into a Rule 56 motion for summary judgment pursuant to Rule 12(d), and (2) provide Plaintiffs with an opportunity to respond after conducting adequate discovery under Rule 56(d).

LEGAL STANDARDS

When deciding a motion to dismiss under Rule 12(b)(6), courts are precluded from considering evidence extrinsic to the complaint unless (1) the ***document*** is incorporated by

reference, or (2) the *adjudicative fact*³ is subject to judicial notice pursuant to Fed. R. Evid. 201. Should a court go beyond these restrictions, the court must convert the 12(b)(6) motion into a Rule 56 summary judgment motion, and it must give the nonmoving party an opportunity to respond after conducting appropriate discovery. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002); Rules 12(b), 12(d), 56(d); *Global Network Commc'ns, Inc. v. City of N.Y.*, 458 F.3d 150, 155 (2d Cir. 2006) (“[T]he conversion of a Rule 12(b)(6) motion into one for summary judgment under Rule 56 when the court considers matters outside the pleadings is *strictly enforced* and *mandatory*.”). In other words, if the Court decides to consider Defendants’ extrinsic evidence, it is “obligated to convert the motion to one for summary judgment and give the parties an opportunity to conduct appropriate discovery and submit the additional supporting material contemplated by Rule 56.” *Chambers*, 282 F.3d at 154.

A. The Incorporation By Reference Doctrine

It is well established that, when deciding a Rule 12(b)(6) motion to dismiss, a court must only consider the complaint, documents incorporated into the complaint, and documents attached to the motion to dismiss so long as “the complaint relies heavily upon” those documents’ “terms and effect[,]” “no disputes exist regarding the authenticity or accuracy of the document[s][,],” and it is “clear that there exist no material disputed issues of fact regarding the relevance of the document[s].” *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010).

The Second Circuit has explained that the incorporation by reference doctrine does not apply to any and all documents that might be referenced, cited, or relied upon in a complaint.

³ “Adjudicative facts” are “the facts of the particular case.” Fed. R. Evid. 201(a) Advisory Committee’s Note. *See Khoja v. Orexigen Therapeutics*, 899 F.3d 988, 1000 n.5 (9th Cir. 2018) (“*An irrelevant fact could hardly be an adjudicative fact . . .*”) (citing 21B Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure* § 5104, at 156 (2d ed. 2005)).

See Chambers, 282 F.3d at 153. “[E]ven offering ‘limited quotations’ from the document is not enough.” *Goel v. Bunche Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016). Rather, this principle requires that “the complaint rel[y] heavily upon the documents’ terms and effect,” rendering the document “integral” to the complaint.⁴ *Chambers*, 282 F.3d at 153; *see also Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) (“Even if not attached or incorporated by reference, a document upon which the complaint solely relies and which is *integral* to the complaint may be considered by the court in ruling on such motion.”). For example, the integral document doctrine may apply when “a plaintiff’s claim about insurance coverage is based on the contents of a coverage plan, . . . when a plaintiff’s claim about stock fraud is based on the contents of SEC filings,” *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003), or when a plaintiff’s claim about defamatory statements is based on the contents of a newspaper article, *see Horsley v. Feldt*, 304 F.3d 1125, 1135 (11th Cir. 2002). The Court may, for example, verify that an allegedly false statement was in fact made in a particular document because that document is central to Plaintiffs’ securities fraud claim. “In most instances where this exception is recognized, the incorporated material is a contract or other legal document containing obligations upon which the plaintiff’s complaint stands or falls, but which for some reason—usually because the document, read in its entirety, would undermine the legitimacy of the plaintiff’s claim—was not attached to the complaint.” *Goel*, 820 F.3d at 559. However, even if a document is “integral” to the plaintiff’s complaint, “it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document.” *DiFolco*, 622 F.3d at 111.

Significantly, the incorporation by reference doctrine is not a license for Defendants to

⁴ For simplicity’s sake, and in light of existing case law, Plaintiffs sometimes refer to the incorporation doctrine and the integral document doctrine interchangeably herein. Plaintiffs view the integral document doctrine as applying to those documents that are deemed *implicitly* incorporated by reference as a matter of law.

poison the well with self-serving hearsay. Even if a document is incorporated by reference, the doctrine does not permit the court to assume the truth of its contents. *See Roth*, 489 F.3d at 509; *In re Lehman Bros. Sec. and ERISA Litig.*, 799 F. Supp. 2d 258, 273 (S.D.N.Y. 2011) (stating that a document integral to the complaint can be “properly considered, albeit not for the truth of the matters asserted”); *see also Orexigen Therapeutics*, 899 F.3d at 1003 (“[I]t is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint.”). Tellingly, “were the Court to assume the truth of all documents incorporated by reference [], that would mean assuming the truth of all of Defendants’ allegedly false or misleading statements. That cannot be the intended result of the cases Defendants cite, or it would be impossible ever to successfully plead a fraud claim.” *In re Ecotality, Inc. Sec. Litig.*, No. 13–03791–SC, 2014 WL 4634280, at *3 n.2 (N.D. Cal. Sept. 16, 2014).

And not to be forgotten, a court considering a document as being incorporated by reference must still do so within the limits of Rule 12(b)(6). That is, “even when the court is allowed to consider these extrinsic materials, it must do so under the appropriate standard of Rule 12(b)(6), so that materials must be viewed in the light most favorable to the plaintiffs, and all reasonable inferences from them must be drawn in plaintiff’s favor.” 2-12, James Wm. Moore, *et al.*, *Moore’s Federal Practice*, §12.34[2] (2015).

B. Judicial Notice Under Federal Rule of Evidence 201

Pursuant to Federal Rule of Evidence 201, a court is permitted to consider matters extraneous to the complaint by taking judicial notice of *adjudicative facts* that are not subject to reasonable dispute because they are (1) generally known within the trial court’s territorial jurisdiction (“Generally Known”); or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned (“Readily Determinable”). Fed. R. Evid.

201(b); *see also United States v. Bryant*, 402 F. App'x 543, 545 (2d Cir. 2010). Rule 201(e) provides that “a party is entitled to be heard on the propriety of taking judicial notice and the nature of the fact to be noticed.” Fed. R. Evid. 201(e).

The Second Circuit has admonished that “caution must be used in determining that a **fact is beyond controversy**.” *International Star Class Yacht Racing Ass’n v. Tommy Hilfiger U.S.A., Inc.*, 146 F.3d 66, 71 (2d Cir. 1998). Facts appropriate for judicial notice must meet either of Rule 201’s tests for indisputability: “they should be common knowledge or derived from an unimpeachable source.” *Alvarez v. County of Orange*, 95 F. Supp. 3d 385, 398 (S.D.N.Y. 2015) (quoting *Tommy Hilfiger U.S.A., Inc.*, 146 F.3d at 70). “A high degree of indisputability is the essential prerequisite.” Fed. R. Evid. 201(a) Advisory Committee’s Note (stating that “adjudicative facts” are usually established “through the introduction of evidence, ordinarily consisting of the testimony of witnesses[,]” and that “[i]f particular facts are outside of reasonable controversy, this process is dispensed with as unnecessary[.]”).

As a result, courts typically only take judicial notice of readily verifiable matters such as “(1) scientific facts: for instance, when does the sun rise or set; (2) matters of geography: for instance, what are the boundaries of a state; or (3) matters of political history: for instance, who was president in 1958.” *Shahar v. Bowers*, 120 F.3d 211, 214 (11th Cir. 1997).

“Because judicial notice forecloses the parties’ opportunity to use rebuttal evidence, cross-examination, and argument to attack such evidence, caution must be used in determining that a fact is beyond controversy under Rule 201(b).” *Bruce Lee Enters. LLC v. A.V.E.L.A., Inc.*, No. 10 CV 2333(KMW), 2013 WL 822173, at *9 (S.D.N.Y. Mar. 6, 2013). Consequently, it is inappropriate for a court to take judicial notice not only of facts that are directly in dispute, but also of facts that are **disputable**. Indeed, a court “should not use judicial notice to generate an

evidentiary record and then weigh evidence—which plaintiffs have not had the opportunity to challenge—to dismiss plaintiffs['] complaint.” *In re Network Equip. Techs., Inc., Litig.*, 762 F. Supp. 1359, 1363 (N.D. Cal. 1991) (“While defendants['] arguments on the facts may ultimately prevail upon a motion for summary judgment or at trial, they do not create a basis for dismissing plaintiffs’ complaint.”).

“[A] court cannot take judicial notice of a fact that would be inadmissible if it were offered as evidence.” 21B Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice & Procedure: Evidence* §5106.4 (2d ed. Supp. 2018). Consequently, when taking judicial notice of public documents on a motion to dismiss, a court may not—in violation of the hearsay rules—assume the truth of the factual matters asserted in those documents. *See Global Network*, 458 F.3d at 156 (finding judicial notice improper where court “relied on those materials to make a finding of fact that controverted the plaintiff’s own factual assertions”); *Staehr v. Hartford Fin. Servs. Grp.*, 547 F.3d 406, 425 (2d Cir. 2008) (noting that judicial notice of public documents was proper specifically because “[n]one of these materials were offered for the truth of the matter asserted”); *Pabon v. Barclays Bank PLC*, No. 14–cv–7897 (LAK), 2015 WL 5834796, at *1 (S.D.N.Y. Sept. 30, 2015) (“[T]o the extent this Court takes judicial notice of certain other documents outside the complaint, it does so only as evidence of what those documents say, not the truth of the matters asserted.”); *In re Teligent Inc.*, 380 B.R. 324, 329 n.2 (Bankr. S.D.N.Y. 2008) (“The taking of judicial notice simplifies the process of authenticating a document, but does not automatically render the document admissible in the face of a hearsay objection.”).⁵

That is, ***assuming such facts are relevant***, a court may take judicial notice of the existence,

⁵ *Accord Cal. ex rel. RoNo, L.L.C. v. Altus Fin. S.A.*, 344 F.3d 920, 931 n.8 (9th Cir. 2003) (“[W]hen a court takes judicial notice of another court’s opinion, it may do so not for the truth of the facts recited therein, but for the existence of the opinion.”).

effect, and date of public documents, as well as statements the documents contain; the court may not, however, take judicial notice of the truth of the documents' contents.

As is the case with incorporation by reference, when judicial notice of a fact is appropriate, the import of that fact is still subject to the confines of Rule 12(b)(6). *See Zak v. Chelsea Therapeutics, Ltd.*, 780 F.3d 597, 607 (4th Cir. 2015) (“[W]hen a court considers relevant facts from the public record at the pleading stage, the court must construe such facts in the light most favorable to the plaintiffs.”); 2-12, James Wm. Moore, et al., *Moore’s Federal Practice*, § 12.34[2] (2015). Consequently, a court may not “take judicial notice of facts favorable to [d]efendants that could reasonably be disputed.” *United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 999 (9th Cir. 2011). A court cannot use judicial notice to “stack[] facts extracted from secondary sources to construct an alternative narrative, at odds with the [complaint’s] well-pled allegations.” *In re Interest Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 481 (S.D.N.Y. 2017). In point of fact, it would be inherently unreasonable to draw any inferences—much less those against a non-moving party—based on inadmissible hearsay or evidence that is otherwise inadmissible under the Federal Rules of Evidence.⁶

ARGUMENT

I. DEFENDANTS’ JUDICIAL NOTICE REQUESTS ARE DEFECTIVE BECAUSE THEY DO NOT IDENTIFY THE ADJUDICATIVE FACTS THAT THE COURT IS BEING ASKED TO DECIDE UNDER RULE 201

As the proponents of the evidence, Defendants bear the burden of persuading the Court that the evidence being submitted may properly be considered for the purpose it is being offered.

See In re Tyrone F. Conner Corp., Inc., 140 B.R. 771, 781 (Bankr. E.D. Cal. 1992) (“[A] party

⁶ Given that inadmissible hearsay and attorney testimony are not subject to consideration *at trial*, *see, e.g., MF Global Holdings Ltd. v. PricewaterhouseCoopers LLP*, 232 F. Supp. 3d 558, 568 (S.D.N.Y. 2017), it stands to reason *a priori* that consideration of Defendants’ inadmissible evidence to draw negative inferences against Plaintiffs is likewise inappropriate *on a Rule 12(b)(6) motion*.

requesting judicial notice bears the burden of persuading the trial judge that the fact is a proper matter for judicial notice.”); Fed. R. Evid. 201(c). As the requesting parties, Defendants must specify which adjudicative facts the Court is being asked to decide, and Defendants bear the burden under Rule 201 of demonstrating how each of those facts is Generally Known or Readily Determinable from the materials submitted. *See Guzman-Ruiz v. Hernandez-Colon*, 406 F.3d 31, 36 (1st Cir. 2005) (stating that the district court was “amply justified” in refusing to take judicial notice where, *inter alia*, the party “made no attempt to specify what ‘adjudicable facts’ met the requirements of [Rule] 201”); *Clark v. Kitt*, No. 12-CV-8061 (CS), 2014 WL 4054284, at *14 (S.D.N.Y. Aug. 15, 2014) (denying request to judicially notice database as it was tantamount to “asking th[e] Court to do counsel’s legwork by sorting” through the database); *see also NDX Advisors, Inc. v. Advisory Financial Consultants, Inc.*, No. C 11-3234 SBA, 2012 WL 174942, at *3 (N.D. Cal. Jan. 20, 2012) (denying request where defendant failed to provide citations to specific documents, and noting that courts are “not obligated to consider matters not specifically brought to its attention.”).

Defendants’ conclusory request for consideration of their extrinsic evidence is improper, vague, and unsupported by specific arguments. Critically, Defendants do not specify which adjudicative facts they want the Court to decide by judicial notice. Rather, Defendants cryptically request in a cursory footnote that the Court “take judicial notice of all public documents annexed to the Affirmation of Aurora Cassirer in Support of Defendants’ Motion to Dismiss[.]” Br. at 2 n.1. As an initial matter, arguments which appear in footnotes are generally deemed to be waived. *DeAngels v. Corzine*, No. 11 Civ. 7866(VM)(JCF), 2015 WL 585628, at *7 n.8 (S.D.N.Y. Feb. 9, 2015). More importantly, it is indisputable that Defendants “***made no attempt to specify what adjudic[ative] facts [meet] the requirements of Federal Rule of***

Evidence 201.” *Guzman-Ruiz*, 406 F.3d at 36. Given Defendants’ failure to identify which facts the Court is being asked to decide, it is necessarily impossible to determine if those “facts” are Generally Known or Readily Determinable under Rule 201.⁷ Accordingly, judicial notice of any fact based on Defendants’ evidence is improper, and Defendants’ Exhibits and all arguments based thereon should be stricken. *See Natural Resources Defense Council, Inc. v. U.S. Food and Drug Admin.*, 884 F. Supp. 2d 108, 115 n.5 (S.D.N.Y. 2012) (stating “[a] court has inherent authority to strike any filed paper which it determines to be abusive or otherwise improper under the circumstances” and collecting cases).

Additionally, Defendants do not request that the Court consider any Exhibit under the incorporation by reference doctrine, nor do they explain how any of their Exhibits are incorporated by reference into the AC. Br. at 2 n.1. As a result, Defendants have waived any argument that the Exhibits are incorporated by reference. *See In re Toor*, No. 16-CV-1773 (JCH), 2017 WL 1712511, at *2 (D. Conn. May 1, 2017) (declining to consider issue because there was no “argument on the topic[] in [the] opening brief”).

In light of Defendants’ gamesmanship, Plaintiffs have had no choice for this motion but to comb through hundreds of pages of Exhibits and Defendants’ MTD in an attempt to guess which adjudicative facts Defendants may subsequently ask the Court to judicially notice and which documents Defendants may belatedly argue are incorporated by reference. Plaintiffs’ efforts are further hindered by the fact that (1) the extrinsic evidence does not always support the propositions for which Defendants appear to cite their Exhibits; and (2) Defendants’ tactical

⁷ The notice of motion accompanying the Brief likewise makes no mention of the relief sought with respect to judicial notice or the legal basis for the requested relief, in violation of Local Civ. R. 7.1(a). *See* ECF No. 47; Local Civ. R. 7.1(a)(1) (requiring that the “notice of motion” accompanying a motion “specify the applicable rules or statutes pursuant to which the motion is brought,” and the “relief sought by the motion”).

vagueness often conceals the improper hearsay purpose for which much of the evidence appears to be proffered. *Cf. Orexigen Therapeutics*, 899 F.3d at 1005 (cautioning that mistakenly cited documents happen when “parties pile on volumes of exhibits to their motions”).

II. DEFENDANTS’ EXTRINSIC EVIDENCE IS INADMISSIBLE FOR THE PURPOSES THE EVIDENCE APPEARS TO BE OFFERED

A. SEC Forms 4 And NASDAQ Trading Activity Report

The Forms 4 (Exs. 41-43) and NASDAQ Trading Activity Report (“NASDAQ Report”) (Ex. 44) are neither cited in nor referenced in the AC, and therefore are not incorporated by reference. *Roth*, 489 F.3d at 509.

Defendants appear to cite SEC Forms 4 (Exs. 41-43) and the NASDAQ Report (Ex. 44) to prove that Defendants made no “stock sales during the class period,” Br. at 22-23, even though Plaintiffs allege that Ohr itself sold more than \$62 million in stock, ¶128. While a court may take judicial notice that Defendants filed the Forms 4 with the SEC, if those facts alone were relevant, a court may not take judicial notice or otherwise presume the truth of the statements within the documents, *i.e.*, that the Forms 4 accurately reflect all trades made by Defendants on that day or any other. Such specific facts are not Generally Known, *see Bowers*, 120 F.3d at 214, nor are they Readily Determinable because the “facts” in the Forms 4 concerning the stock sales are subject to reasonable dispute and are inadmissible hearsay. *See New Jersey Carpenters Health Fund v. Royal Bank of Scotland Group, PLC*, 709 F.3d 109, 127 (2d Cir. 2013) (“[C]ourts considering a motion to dismiss may take judicial notice of the *fact* that press coverage contained certain information so long as they do not rely on the truth of that information.”); *In re Thornburg Mortg., Inc. Sec. Litig.*, No. CIV 07–0815 JB/WDS, 2009 WL 5851089, at *3 (D.N.M. Dec. 21, 2009) (declining to notice the truth of the Forms 4 and noting that “the contents of the SEC filings is *potentially* false, as the documents were created by

individuals, fallible and potentially prone to untruth as humans sometimes tend to be[.]”).

Moreover, *even if the Court assumes arguendo that the Forms 4 are accurate*, they do not establish the fact that Defendants made no stock sales during the Class Period. At best, the representations in the documents are only true for the dates and transactions listed on the Forms 4. The absence of Forms 4 for the remaining dates during the Class Period is not evidence of the absence of sales on those remaining days. Indeed, the only fact Readily Determinable from the Forms 4 is what Defendants reported to the SEC—nothing more can be accurately and readily determined. *Wagner v. Royal Bank of Scotland Group PLC*, No. 12 Civ. 8726(PAC), 2013 WL 4779039, at *3 (S.D.N.Y. Sept. 5, 2013) (“Defendants rely on Form 4 not to demonstrate that certain statements were included or omitted, but rather to establish the truth of the matters asserted in those statements. That is not permitted.”); *Patel v. Parnes*, 253 F.R.D. 531, 546 (C.D. Cal. 2008) (“It is appropriate for the court to take judicial notice of the content of the SEC Forms 4 and the fact that they were filed with the agency. The truth of the content, and the inferences properly drawn from them, however, is not a proper subject of judicial notice under Rule 201.”).

The SEC itself declines to take Forms 4 at face value. *See, e.g.*, Press Release, SEC, Corporate Insiders Charged for Failing to Update Disclosures Involving “Going Private” Transactions, <https://www.sec.gov/news/pressrelease/2015-47.html> (Mar. 13, 2015) (Several respondents “only disclosed their transactions in company securities months or years after the fact, not within two business days, as required for these disclosures by insiders.”).

It follows then that the Forms 4 must be disregarded entirely because Defendants’ assertion that these were the only trades made by Defendants during the Class Period and that all of their trades were reported in a truthful manner to the SEC are only relevant if these assertions

are improperly assumed true. *See Maiman v. Talbott*, No. SACV 09-0012 AG (ANx), 2010 WL 11421950, at *7 (C.D. Cal. Aug. 9, 2010) (declining to “take judicial notice of defendants’ stock purchases reflected in Forms 4” because judicial notice of SEC filings “should not be taken of the truth of their contents”); *City of Sterling Heights Gen. Emples. Ret. Sys. v. Hospira, Inc.*, 2013 WL 566805, at *12 (N.D. Ill. Feb. 13, 2013) (if the court did not consider the truth of the sales data in Forms 4, then the documents “would not be relevant to the issue of scienter”); *In re Thornburg*, 2009 WL 5851089, at *3.

Additionally, the AC does not allege any facts regarding the Individual Defendants’ sales, and it is “inappropriate for the Court to consider contrary evidence from Defendants at this stage.” *In re ECTotality*, 2014 WL 4634280, at *4. Defendants’ request to judicially notice the Forms 4 should be denied on this basis alone. *See id.* (denying judicial notice and noting that “*Tellabs* does not grant defendants an opportunity to provide competing evidence at the pleadings stage.”).

As with the Forms 4, Defendants apparently cite the NASDAQ Report, Ex. 44, to prove that there were no insider sales by Defendants. Br. at 23, n.30. However, notice of the NASDAQ Report is improper because its contents are being offered for the same hearsay purposes as the Forms 4. The report claims it is “derived from Forms 3 and 4 filings filed with the [SEC]” and constitutes double hearsay given that it relies on the hearsay asserted in the Forms 4. Ex. 44 at 2. Nor is the NASDAQ Report an SEC filing or press report subject to judicial notice. *See In re OSI Pharmaceuticals, Inc. Sec. Litig.*, No. 04-CV-5505 (JS)(WDW), 2007 WL 9672541, at *4 (E.D.N.Y. Mar. 31, 2007) (“[T]he Court will not notice documents adduced by Defendants that are merely available on the internet or otherwise available to the public when it can be plausibly argued that the source or accuracy of the document can

reasonably be questioned.”). Crucially, the Nasdaq Report does not even prove Defendants’ contention: the report only covers 12 months of the multi-year Class Period in this action. *Compare* Ex. 44 at 2, with ¶131 (Class Period dates). Accordingly, judicial notice of the NASDAQ Report is inappropriate.

B. Ohr SEC Filings Concerning Certain Defendants’ Work Histories

Defendants appear to cite Exhibits 1-3 to prove that Taraporewala is a “veteran healthcare executive,” Backenroth has “experience in financing biotechnology companies,” and that Ohr is “a rollup of undervalued . . . assets,” insinuating that Squalamine was one such undervalued asset. Br. at 3 n.2. These supposed facts are not Generally Known, and are irrelevant to the MTD unless the conclusory hearsay within the Exhibits is assumed to be true. *See City of Austin Police Ret. Sys. v. Kinross Gold Corp.*, 957 F. Supp. 2d 277, 288 (S.D.N.Y. 2013). Accordingly, judicial notice of these facts is improper.

Exhibit 3 is neither cited in nor referenced in the AC, let alone “integral to the complaint,” and therefore is not incorporated by reference. *Roth*, 489 F.3d at 509. Although the AC cites to Exhibit 2 at ¶¶28-29 for the limited purpose of providing background on Ohr, and Exhibit 1 at ¶42 for background on Taraporewala and Backenroth, none of Plaintiffs’ claims “relies heavily upon” these Exhibits. *DiFolco*, 622 F.3d at 111; *Goel*, 820 F.3d at 559 (noting that “offering ‘limited quotations’ from the document is not enough” to consider a document under the incorporation by reference doctrine). Assuming *arguendo* that Exhibits 1 and 2 are incorporated by reference, Defendants offer them for improper hearsay purposes, as explained in the preceding paragraph. *Lehman Bros.*, 799 F. Supp. 2d at 273. Accordingly, Exhibits 1-3 cannot be considered with Defendants’ MTD.

C. Ohr SEC Filings And Press Releases Offered For Cautionary Statements

Defendants cite Exhibits 35-40 in the context of their argument that Defendants’

statements are protected by the PSLRA's safe harbor-for "forward-looking" statements, and Defendants appear to cite the Exhibits for their "risk disclosures." Br. at 19. & n.26. However, under the PSLRA's safe harbor, cautionary language must be *in the same document* as the statements challenged as false and/or misleading in order for any such cautionary language to provide a safe harbor. 15 U.S.C. § 78u-5(c)(1)(A)(i) (safe harbor applies only to forward-looking statements "accompanied by meaningful cautionary" language). Therefore, the fact that certain risk disclosures were made in Exhibits 35-37, and 39 is irrelevant because Plaintiffs do not allege any false and/or misleading statements in those documents. *See Orexigen Therapeutics*, 899 F.3d at 1000 n.5. As irrelevant facts, they are not "adjudicative facts" subject to judicial notice under Rule 201. *Id.* With respect to exhibits 38 and 40, although Defendants have failed to justify their consideration under either extrinsic evidence exception, Plaintiffs do not object to notice of these warnings to the extent they are offered to "determine *what* the documents stated, and *not to prove the truth of their contents*" with respect to Defendants' safe harbor argument.⁸ *Roth*, 489 F.3d at 509 (original emphasis). Plaintiffs do, however, object to notice of these warnings to the extent they are offered to prove the proposition that the warnings were consistent with Ohr's disclosure on January 5, 2018, which proposition Plaintiffs dispute. *See* ¶¶75, 113-14, 142, 150; Br. at 30 n.34; *Kinross*, 957 F. Supp. 2d at 288 (denying judicial notice request because exhibits were "of no assistance to Kinross except if taken for the truth" and that the "causal link not a fact generally known within the Court's jurisdiction, but by their nature, the causes of a change in development plans may be multiple and/or disputed"); *Acquest Holdings, Inc. v. Travelers Casualty and Surety Company of America*, 217 F. Supp. 3d 678, 685

⁸ While these risk disclosures appear to be offered for PSLRA safe harbor purposes, Plaintiffs intend to make clear in their opposition to the MTD that Defendants' actionable statements are not forward-looking statements subject to protection of the PSLRA's safe harbor.

(W.D.N.Y. 2016) (“Th[e] factual dispute weighs against deeming these documents incorporated by reference or integral to the Complaint.”).

D. SEC Filings And Press Releases Touting Squalamine

Defendants appear to cite Exhibits 5-10, 14-16, and 46—Genaera’s SEC filings—and Exhibits 19, 31-33, and 45—Ohr’s SEC filings and press releases—to self-servingly assert, *inter alia*, that Squalamine’s early clinical data was positive, Br. at 4, 4 n.4 (citing Exs. 5-10); to dispute Plaintiffs’ allegations regarding the cancellation of Genaera’s Squalamine trials, Br. at 5, 5 n.7 (citing Exs. 14-16); to otherwise tout Squalamine as a promising drug, Br. at 6 (citing Ex. 19), 13 n.22 (citing Exs. 31-33), and 33 (citing Ex. 46); and to dispute Plaintiffs’ allegations regarding the failure of Ohr’s MAKO Trial, Br. at 30 (citing Ex. 45). These Exhibits and the purported facts therein are not judicially noticeable, as an initial matter, because they are not Generally Known, *see Bowers*, 120 F.3d at 214. The Exhibits are also not judicially noticeable because: (1) several of the Exhibits are irrelevant, confusing, and prejudicial; (2) several of the Exhibits appear to be cited for the opinions—and not the facts—contained therein; and (3) all of the Exhibits appear to be offered for inadmissible hearsay purposes.

Exhibits 5-10, 14-16, and 46 predate Genaera’s termination of its Squalamine trials in January 2007, *see* ¶40. Consequently, the purported facts in the Exhibits, such as those concerning some of Genaera’s early clinical data, are irrelevant to Genaera’s subsequent termination of its Squalamine program based on the information then available. An irrelevant fact is “hardly . . . an adjudicative fact” subject to judicial notice. *Orexigen Therapeutics*, 899 F.3d at 1000 n.5. And, even if these Exhibits are somehow minimally relevant, their probative value is substantially outweighed by their ability to confuse the issues given the date of the clinical data results cited versus the clinical data available when Genaera quit developing Squalamine—not to mention the prejudice Plaintiffs suffer in being unable to verify these

documents’ assertions without discovery. *See Rodriguez v. Bear Stearns Companies, Inc.*, No. 07-cv-1816 (JCH), 2009 WL 995865, at *12 (D. Conn. Apr. 14, 2009) (declining to take judicial notice “because to do so would risk confusion of the issues”); Fed. R. Evid. 403. Accordingly, judicial notice of Exhibits 5-10, 14-16, and 46 should be denied.

Judicial notice of various purported opinions about Squalamine in Exhibits 5-7, 9, 14-16, and 31-33 is also clearly improper. *See* Br. at 4 n.4 (citing Exs. 5-7 for the opinion that the results in these Exhibits “demonstrated” Squalamine’s effect when dosed weekly); *Id.* (citing Ex. 9 for the opinion that the results in this Exhibit “suggested a differentiated mechanism of action”); *Id.* at 5 n.7 (citing Exs. 14, 15, and 16, for the opinions that Genaera did not terminate its clinical trials for “lack of efficacy[.]” that early clinical data was “positive” and “encourag[ing][.]” and that Squalamine “consistently stabilizes or improves vision”); *Id.* at 13 (citing Exs. 31-33 for the opinion that the individuals quoted in these Exhibits found Squalamine to be “promising”). The text of Fed. R. Evid. 201 is explicit—***judicial notice can only be taken of “facts[.]”*** Opinions, by their very nature, are distinct from facts. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1325 (2015) (noting that “[a] fact is a thing done or existing or [a]n actual happening[.]” whereas an opinion “is a belief[, or view, or a sentiment which the mind forms of persons or things”). Thus, courts have declined to take judicial notice of ***opinions***, including medical opinions. *See Gladu v. Correct Care Solutions*, No. 2:17-cv-00504-JAW, 2018 WL 3122219, at *3 n.3 (D. Me. June 26, 2018) (noting that medical opinions “do not constitute facts that are not subject to reasonable dispute as contemplated by Federal Rule of Evidence 201[.]”); *Chapman University v. Atlantic Richfield Co.*, No. CV 12-05680 DOC (ANx), 2013 WL 3946117, at *3 (C.D. Cal. July 30, 2013) (“[T]he Court is not permitted to take notice concerning one party’s opinion as to how the recognized

documents and their facts should be interpreted.”). Further, the AC alleges—contrary to Defendants’ say so—that Genaera terminated its development of Squalamine for the treatment of Wet AMD **because** Genaera concluded it was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis. ¶40. Accordingly, taking judicial notice of the opinions in Exhibits 5-7, 9, 14-16, and 31-33 is improper.

In any case, the supposed “facts” in Exhibits 5-10, 14-16, 19, 31-33, and 45-46 are not Readily Determinable because the documents are being offered for a hearsay purpose. *See* Br. at 4 n.4 (citing Exs. 5-10), 5 n.7 (citing Exs. 14-16), 6 (citing Ex. 19), 13 n.22 (citing Exs. 31-33), 30 (citing Ex. 45), 33 (citing Ex. 46). In fact, some of these Exhibits do not even say what Defendants purport they say—Exhibits 31-33, for example, do not assert any such consensus regarding Squalamine, or that the quoted individuals are “leading scientists” in the wet-AMD field. *Compare* Br. at 13. 13 n.22, *with* Exs. 31 at 1, 32 at 1, *and* 33 at 1. Exhibit 14 appears to be cited to prove that Genaera’s Squalamine studies “foundered for lack of patient enrollment and were ultimately discontinued” when that Exhibit states no such thing. *Compare* Br. at 5, *with* Ex. 14. Indeed, judicial notice is especially inappropriate where, as is the case here, Defendants are “stacking facts extracted from” these Exhibits “to construct an alternative narrative [about Squalamine], at odds with the [AC’s well-pled allegations” and, in some instances, the Exhibits themselves. *In re Interest Rate Swaps*, 261 F. Supp. 3d at 481. Accordingly, judicial notice of the facts in Exhibits 5-10, 14-16, 19, 31-33, and 45-46 should be denied. *See Kinross*, 957 F. Supp. 2d at 288 (denying judicial notice request because exhibits were “of no assistance to Kinross except if taken for the truth”).

As well, Exhibits 5-9, 14-16, 32-33, and 19 are neither cited nor referenced in the AC, let alone “integral to the complaint,” and therefore are not incorporated by reference. *Roth*, 489

F.3d at 509. Although the AC cites to Genaera's March 1, 2006 press release annexed to its Form 8-K (Ex. 10) and Genaera's March 7, 2006 Form 10-K (Ex. 46) for background on Genaera's earlier studies, ¶38, and Ohr's March 29, 2016 press release (Ex. 31) for background concerning Ohr's MAKO Trials, ¶70, these Exhibits are not integral to Plaintiffs' claims. Indeed, Plaintiffs do not allege any false and/or misleading statement from these Exhibits. *See Goel*, 820 F.3d at 559 (explaining that "merely mentioning" a document or offering "limited quotation[s]" from it "is not enough[]" for incorporation by reference); *Sviridyuk v. BAC Home Loan Servicing, LP*, No. 3:11-cv-01107-SI, 2012 WL 174791, at *2 (D. Or. Jan. 20, 2012) (stating that even a document that "may constitute important evidence going to the merits of [p]laintiff's claim . . . does not form the basis of [p]laintiff's claim as alleged[]"). Even assuming *arguendo* that Exhibits 10, 31, and 46 were incorporated by reference, it would be improper for the Court to consider the documents for the truth of the matters asserted therein. *See In re Lehman Bros.*, 799 F. Supp. 2d at 273; *ECotality*, 2014 WL 4634280, at *3 n.2.

Although the AC cites Exhibit 45, the January 5, 2018 press release and 8-K, for Ohr's disclosure of its Phase III MAKO Trial results (¶75), this document is not integral to Plaintiff's claims because there is no allegation that any investor was misled by them. *See Missud v. Oakland Coliseum Joint Venture*, No. 3:11-cv-01107-SI, 2013 WL 812428, at *1 (N.D. Cal. Mar. 5, 2013) (declining to consider defendants' own website because "there [were no] allegation[s] that any [p]laintiff relied on these webpages or was misled by these webpages"); *Sviridyuk*, 2012 WL 174791, at *2 (Although a document "may constitute important evidence going to the merits of [p]laintiff's claim . . . it does not form the basis of [p]laintiff's claim[.]"). Even assuming *arguendo* that Exhibit 45 was incorporated by reference, it would be improper for the Court to consider the document to dispute Plaintiffs' loss causation allegations as

explained above. *See supra* §II.C.

E. December 22, 2016 Seeking Alpha Transcript

Defendants appear to cite a Seeking Alpha transcript of Ohr’s December 22, 2016 Q4 2016 Earnings Call (Ex. 34) (“Seeking Alpha Transcript”) to prove that Ohr “made clear time and again that they relied upon the CATT Trial as most comparable to the Lucentis monotherapy control arm utilized in the IMPACT Trial.” *See Br.* at 16.

The Seeking Alpha Transcript was neither cited nor referenced in the AC, let alone “integral to the complaint,” and therefore is not incorporated by reference. Rather, the AC cites the transcript published by **Bloomberg L.P.** (“Bloomberg Transcript”) for what was said on the call.⁹ ¶119 (“Ohr Pharmaceutical Inc., Conference Call, Bloomberg Transcript (Dec. 22, 2016)”); *Roth*, 489 F.3d at 509 (doctrine applies to “documents”).

Defendants cite the wrong transcript solely to dispute Plaintiffs’ allegations, which of course is precluded under Rule 12(b)(6). *See In re Interest Rate Swaps*, 261 F. Supp. 3d at 481 (judicial notice cannot be used to “stack[] facts extracted from secondary sources to construct an alternative narrative, at odds with the [complaint’s] well-pled allegations”). That is, Plaintiffs claim that Ohr expressly and misleadingly compared the interim results of the IMPACT Trial’s Lucentis Monotherapy Arm to the historical results of previous Lucentis monotherapy “studies.” *See, e.g.*, ¶¶82-92. Plaintiffs clearly allege that Ohr expressly compared the IMPACT Trial’s data to the results of “previous clinical studies”—not just the Lucentis monotherapy results of the CATT Trial. ¶¶82, 84. The Bloomberg Transcript quoted in ¶119 **corroborates** Plaintiffs’ claims as the Bloomberg Transcript quotes Slakter as using the plural “studies” just as is alleged

⁹ Bloomberg L.P. is a world-renowned financial, software, data, and media company founded by former New York City mayor Michael Bloomberg. *See* [https://en.wikipedia.org/wiki/Bloomberg L.P.](https://en.wikipedia.org/wiki/Bloomberg_L.P.)

in the AC. For that matter, the use of the singular “study” in the Seeking Alpha Transcript does not make sense when read in the context of the remaining language of the sentence and ordinary usage.

Further, the transcript Defendants cite does not support their arguments. The Seeking Alpha Transcript itself says nothing about which of the historical Lucentis monotherapy studies was “**most comparable**” to the IMPACT Trial’s Lucentis Monotherapy Arm, nor does it establish that Defendants made this assertion “time and again.” Indeed, Defendants’ argument that the CATT Trial was the “**most comparable**” trial is inherently inconsistent with Defendants’ arguments elsewhere in their brief that the CATT Trial was the **only** comparable trial and that this opinion was disclosed to investors. *See* Br. at 16 (“[T]he CATT Trial was **the only reasonably comparable historical study to be used** for perspective on the IMPACT Trial’s results.”); *id.* at 26 (“Further, Ohr publicly stated that the CATT Trial of Lucentis was **the comparator** relied upon” and “Defendants’ opinion that **only the CATT Trial** was an appropriate comparable”). In any case, Rule 12(b)(6) does not permit Defendants to distort the record in this manner.

Regardless, the Court may not consider the Seeking Alpha Transcript as it is inadmissible hearsay. The Seeking Alpha Transcript purports to record what was said by participants on the December 22, 2016 earnings call. *See* Ex. 34. It is therefore an out-of-court statement being offered for the truth of the matter asserted therein (namely what Seeking Alpha claims was said). *See* Fed. R. Evid. 801(c). *See Kinross*, 957 F. Supp. 2d at 288 (denying judicial notice request because exhibits were “of no assistance to Kinross except if taken for the truth”).

Moreover, its contents are not Generally Known, and the only Readily Determinable fact from the transcript is what Seeking Alpha transcribed as having been stated during the call. *See*

In re OSI Pharmaceuticals, 2007 WL 9672541, at *5 (declining to take judicial notice of a conference call transcript, as it is “not a matter of public record like an SEC filing[,] [n]or is it otherwise capable of accurate and ready determination from sources whose accuracy cannot reasonably be questioned[.]”). Seeking Alpha itself cautions investors that “[t]here may be errors, omissions, or inaccuracies in our transcripts[,]” and it is therefore not a source whose accuracy cannot reasonably be questioned. Seeking Alpha, *SA Transcripts*, https://seekingalpha.com/page/sa_transcripts (last visited Nov. 13, 2018).

F. Medical Articles On Squalamine And Other Drugs

Defendants appear to offer Exhibits 4, 17-18, 20, and 22-30, which are various articles on Squalamine and other wet-AMD drugs, to build a counternarrative regarding the viability of Squalamine and to dispute Plaintiffs’ allegations. Br. at 4 (citing Ex. 4), 5 (citing Ex. 17), 6 (citing Exs. 18, 20), 8-9 (citing Exs. 22-30).¹⁰ These exhibits are not judicially noticeable because their contents are not Generally Known. These exhibits are also not judicially noticeable because (1) several of the Exhibits are irrelevant, confusing, and prejudicial because they predate Genaera’s termination of Squalamine (Exs. 4 and 17), *see Orexigen Therapeutics*, 899 F.3d at 1000 n.5; *Rodriguez*, 2009 WL 995865, at *12; (2) these Exhibits appear to be cited for their medical opinions, not facts, *see Gladu*, 2018 WL 3122219, at *3 n.3; and (3) in any event, all of these Exhibits appear to be offered for the truth of the matters asserted in them, and to dispute Plaintiffs’ factual allegations, *see Kinross*, 957 F. Supp. 2d at 288.

Additionally, Exhibits 4, 17, 18, 20, 22, 28, 29, and 30 are neither cited nor referenced in the AC, let alone integral to the AC, and therefore are not incorporated by reference. *Roth*, 489

¹⁰ For example, Defendants appear to cite Exhibit 20 to prove that “Ohr’s . . . plan to evaluate Squalamine in clinical trials when used in combination with Lucentis . . . was precisely the type of combination therapy recommended by experts.” Br. at 6 n.12. This is false—the Exhibit does not state any such *recommendation*. Ex. 20 at 6.

F.3d at 509. Exhibits 23-27 are cited in the AC for background information for Plaintiffs' claim concerning the underperforming Lucentis Monotherapy Arm, but Plaintiffs' claims do not solely rely on these documents as Plaintiffs do not allege a false and/or misleading statement from these Exhibits, nor that any investor was misled by these documents. *See Goel*, 820 F.3d at 559 (explaining that "merely mentioning" a document or offering "limited quotation[s]" from it "is not enough[]" for incorporation by reference); *Sviridyuk*, 2012 WL 174791, at *2 (stating that even a document that "may constitute important evidence going to the merits of [p]laintiff's claim" is not incorporated by reference). Assuming *arguendo* that Exhibits 23-27 were incorporated by reference, it would be improper to consider the truth of the matters asserted therein. *See In re Lehman Bros.*, 799 F. Supp. 2d at 273.

G. FDA Documents

1. FDA Labels For LUCENTIS®, VISUDYNE®, And MACUGEN®

Defendants appear to cite to the FDA Labels for LUCENTIS® (Ex. 11), VISUDYNE® (Ex. 12), and MACUGEN® (Ex. 13), to prove various factual propositions. *See Br.* at 4 n.5, 10 n.20. Exhibits 11, 12, and 13 are neither cited nor referenced in the AC, let alone "integral to the complaint," and therefore are not incorporated by reference. *Roth*, 489 F.3d at 509. These exhibits are not judicially noticeable because they are not Generally Known, nor are the facts Defendants appear to seek notice of Readily Determinable from the face of these documents. Lastly, even if the documents actually stated the facts at issue, the documents are clearly being offered for a hearsay purpose and thus cannot be considered by judicial notice or under the incorporation by reference doctrine. *See In re Lehman Bros.*, 799 F. Supp. 2d at 273; *Kinross*, 957 F. Supp. 2d at 288.

2. FDA Guidance On Choice Of A Control Group When Designing A Clinical Trial

Defendants cite FDA Guidance entitled “Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials” (“Guidance”) (Ex. 21), to prove that “historical controls are a poor method to determine the effect of a treatment.” Br. at 7.

The Guidance is neither cited nor referenced in the AC, let alone “integral to the complaint,” and therefore is not incorporated by reference. *Roth*, 489 F.3d at 509.

Judicial notice of the Guidance for the purposes Defendants appear to offer it is improper because the Guidance is irrelevant to Plaintiffs’ claims. The Guidance’s primary goal is to “describe the general principles involved ***in choosing a control group for clinical trials*** intended to demonstrate the efficacy of a treatment and to ***discuss related trial design and conduct issues.***” Ex. 21 at 7. Plaintiffs do not claim that Defendants made false and/or misleading statements regarding the ***design*** of Ohr’s IMPACT Trial; instead, Plaintiffs allege that Defendants misleadingly touted the results from the IMPACT Trial after the fact and assured the market that “the visual acuity gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment[.]” See ¶¶82-112. Defendants were free to design the IMPACT Trial as they pleased; they were not free, however, to then go out and report the Trial’s results by fraudulently comparing them to previous clinical studies. Therefore, the Guidance is irrelevant, and an irrelevant fact is “hardly . . . an adjudicative fact” subject to judicial notice. *Orexigen Therapeutics*, 899 F.3d 988, 1000 n.5. Even if the Guidance were minimally relevant, Defendants improperly seek judicial notice of the guidance to confuse the factfinder and prejudice Plaintiffs by making it appear as if the FDA Guidance relates to something other than guidance on how companies should design clinical studies. See *Rodriguez*, 2009 WL 995865, at *12 (declining to judicially notice document

“because to do so would risk confusion of the issues”); Fed. R. Evid. 403. Accordingly, judicial notice of the Guidance should be denied.

H. Seeking Alpha Article And Law Firm Press Releases

In support of their statute of limitations argument, Br. at 31-34, Defendants cite a Seeking Alpha article entitled “The Ugly Truth Behind Ohr Pharma” in Seeking Alpha’s “Short Ideas” section (“SA Article”) (Ex. 47) and two law firm press releases pertaining to Ohr (Exs. 48 and 49).

These Exhibits are neither cited in nor referenced in the AC, let alone integral to Plaintiffs’ claims, and therefore are not incorporated by reference. *Roth*, 489 F.3d at 509.

The documents are likewise not subject to judicial notice for the purposes they appear to be offered. The SA Article appears to be cited to prove that Ohr bought Squalamine from Genaera for “less than \$100,000,” that the drug was “discarded as unviable,” and that there was a stock surge due to a stock promotion paid for by Ohr management. Br. at 33 & n.38. The SA Article is therefore being offered for a hearsay purpose and is thus inadmissible. Nor have Defendants offered any evidence supporting the notion that an article by an individual investor on Seeking Alpha is a public document, including for example whether Seeking Alpha is a fee-based subscription service and how many readers the supposedly “public” article had. Judicial notice of this blog article is therefore inappropriate, as courts do not “notice documents adduced by Defendants that are merely available on the internet.” *See In re OSI Pharmaceuticals*, 2007 WL 9672541, at *4.

Defendants appear to cite press releases (Exhibits 48 & 49) disseminated by two law firms to prove that in 2015 those firms “published class action notices soliciting Ohr shareholders to form a class action suit against Ohr *for the same or similar allegations as pleaded in this action.*” Br. at 34. The facts being proffered are not Generally Known nor are

they Readily Determinable from the Exhibits, which are themselves silent about the details of these hypothetical class action claims. In fact, no lawsuits were ever filed. Thus it is impossible to determine whether the hypothetical allegations were the same or similar to those pleaded in this action. Given that the Class Period in this case runs through January 4, 2018, such assertions are highly doubtful; and there is zero evidence that some hypothetical action would cover each and every—or any—claim Plaintiffs assert. Lastly, it is inadmissible hearsay to offer these documents to prove that these law firms were doing whatever it is Defendants assert they were doing based on these documents, and therefore the documents are inadmissible.

I. Unsworn Attorney Testimony

In addition to the inadmissible unsworn attorney testimony associated with the extrinsic evidence discussed above, Defendants' MTD contains further unsworn attorney arguments and conclusions that are unsupported by the record or any other citation. *See Bldg. & Constr. Trades Council of Buffalo v. Downtown Dev., Inc.*, 448 F.3d 138, 155 (2d Cir. 2006) (“[A]rguments based on the moving parties’ assertions of fact are inapt on a motion to dismiss.”); *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 449 (4th Cir. 2011) (“[S]tatements by counsel that raise new facts constitute matters beyond the pleadings and cannot be considered on a Rule 12(b)(6) motion.”).

The following assertions are unsworn attorney testimony, are not based on personal knowledge, *see* Fed. R. Evid. 602, are not supported by citations to the AC or other documents properly before the Court, appear to be offered for a hearsay purpose, and as a result of the foregoing are inadmissible:

- “Genaera Corporation was a company founded in 1987 as Magainin Pharmaceuticals.”

Br. at 3.

- “Genaera’s data demonstrated that Squalamine was active *in vitro*, in multiple in-vivo disease models and in clinical trials as a single stand-alone drug (“monotherapy”) for wet AMD.” *Id.* at 4.
- “One of those trials, Study 207, was performed to better understand the drug and to establish possible correlations between toxicity/efficacy parameters and drug concentrations.” *Id.* at 4 n.4.
- “The release of data from Lucentis announced in July 2005 (MARINA study) and in 2006 demonstrated results that were better than those seen with Squalamine alone, but that does not mean that Squalamine did not demonstrate activity in an FDA-approvable endpoint.” *Id.* at 4.
- “Any implication that Dr. Ciulla had any information inconsistent with Defendants’ conclusions and public statements, is not borne out either in the Complaint or in the publications.” *Id.* at 5 n.8.
- “Ohr addressed the dosing deficiency by proposing a topical daily administration route as a way to maintain therapeutic level concentrations as compared to Genaera’s intravenous formulation.” *Id.* at 6.
- “Plaintiffs’ failed attempt at creating an ‘appropriate control group’ involves a comparison of historical Lucentis trials which are not comparable at all. In so doing, Plaintiffs not only ignore basic scientific and FDA guidance, but also show a fundamental lack of understanding of drug development.” *Id.* at 6.
- “The Genaera intravenous infusion (“IV”) which was delivered infrequently (weekly and then monthly) likely did not last above the therapeutic threshold for more than a few days based on pharmacokinetic parameters; thus, resulting in inadequate dosage.” *Id.* at 6

n.10.

- “Moreover, a historical control could only be useful in gaining some perspective of trial results if all parameters were matched between the study and the historical control, including, but not limited to: type of study (randomized vs. nonrandomized, masked vs. unmasked, prospective vs. retrospective); study size; demographics (age, sex, race); lesion type and size; visual acuity; central retinal thickness; treatment naïve or previously treated; treatment regimen (monthly, PRN, treat and extend, etc.); drug (Lucentis vs. Avastin); visit schedule; timing of endpoints; location; and year study was conducted. No study cited in Plaintiffs’ analysis suffices.” *Id.* at 7.
- “The IMPACT Trial was a randomized, double-masked, prospective trial enrolling treatment naïve patients based on specific parameters defined in the protocol.” *Id.* at 7.
- The “comments” on the right side of the table on page 8 of the MTD, and those on the top the same table which state, “PRN studies using 3 loading doses not comparable to IMPACT and CATT single injection PRN regimen” and “Monthly regimen data not applicable to PRN regimens and data.”
- “The above analysis demonstrates that the studies in Plaintiffs’ chart, with the exception of the CATT study, should be excluded from this attempt to retroactively determine an ‘appropriate control group’ standard by virtue of the fact that they are not even remotely comparable.” *Id.* at 9.
- “The table includes very small, uncontrolled and nonrandomized studies, single center trials and retrospective case studies. These are wholly inappropriate comparators versus a randomized, double-masked, multi-center, controlled study like IMPACT.” *Id.* at 9.

- “Multiple data points in the table are incorrect and conflict with the cited papers.”¹¹ *Id.* at 9.
- “Plaintiffs indiscriminately include multiple data points from some studies but not others and incorporate all of the endpoints into the ‘average’ with no supporting rationale.” *Id.* at 9.
- “Twelve-month data endpoints cannot be compared with a 9-month endpoint.” *Id.* at 9.
- “The number of participants in the studies are vastly different or not comparable. Some of the studies have less than 100 subjects and others include more than 1,000.” *Id.* at 10.
- “The analysis fails to account for the totality of vision outcomes including mean VA, 3-line gains, 20/40 functional vision, and final visual acuity.” *Id.* at 10.
- “There simply is no scientifically-sound basis for Plaintiffs’ attempt to compile all data available for a myriad of incomparable clinical trials or to recalibrate Defendants’ sound judgment calls and legally-protected interpretations regarding the IMPACT Trial data.” *Id.* at 10.
- “But alleging prior knowledge of Lucentis alone misses the mark, because what Plaintiffs’ fail to consider is that these same leading scientists—like Defendants—believed in the efficacy of Squalamine.” *Id.* at 12-13.
- “Plaintiffs’ speculation regarding other clinical trials—other trial results widely published in the scientific community, but demonstrably distinguishable—does not vitiate Defendants’ opinion that only the CATT Trial was an appropriate comparable, and, thus, weighs against a finding of scienter.” *Id.* at 26.

¹¹ Defendants claim that the BCVA improvement seen in the GEFAL Trial was “2.9 letters at month 12” instead of 3.63, as alleged in the AC. Br. at 8. However, Defendants are incorrect, as their own Exhibit states that the BCVA improvement was “3.63” at month 12. Ex. 27 at 2305.

As none of the foregoing extrinsic evidence is properly before the Court, *see* Fed. R. Evid. 201(a) & (b), 602, 801(c), 802 and Rule 12(b)(6), the evidence must therefore be stricken from the MTD.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court strike all matters identified herein. Consideration of these materials and all related references in Defendants' briefing is improper unless the Motion to Dismiss is converted into a motion for summary judgment and Plaintiffs are allowed a reasonable opportunity to conduct the necessary discovery. *See* Rule 12(d), 56(d).

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Respectfully submitted,

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